

POLICY PRIORITY:

Protect patients with common sense limits on insurer step therapy protocols.

“Fail first” requirements are inappropriate in bleeding disorders care and can harm patient health. Lawmakers should establish clear timelines and processes for obtaining exceptions to step therapy protocols.

BACKGROUND:

Third-party payers – private insurers, self-insured entities, and government health programs – increasingly look to limit patient access to high-cost drugs. Step therapy is one such restriction: a patient’s health plan requires them to try (and fail on) one or more specified drugs before the payer will cover the product deemed most appropriate by the patient’s doctor.

Payers say step therapy allows them to ensure clinically appropriate care while managing costs. Patient advocates and many provider groups counter that step therapy can hurt patients by delaying or blocking access to care. Common sense guardrails are needed to protect patients against these potential harms.

IMPACT:

Bleeding disorders advocates have consistently argued that it is always clinically inappropriate to subject bleeding disorders patients to step therapy because:

- Clotting factor and newer, non-factor products vary in many important respects (how they work, how long they last, how they are administered, etc.); as such, they are not interchangeable or therapeutically equivalent.
- The potential consequences of a treatment “failure” or delay are extremely serious for any person with a bleeding disorder.
 - There is no clear clinical definition of what constitutes “failure” in the context of bleeding disorders treatment - but
 - Repeated bleeding, or any single major bleed, can cause irreversible injury.
- “Failing” on the wrong treatment will not only hurt patient health: it will also impose extra costs on patients, payers, and the health system as a whole.

POSITION:

Insurer step therapy protocols need to be subject to reasonable constraints to protect patient health.

- Any step therapy protocol must be rooted in clinical evidence.
- Payers should be required to provide a straightforward and time-limited exception process.
- Patients should not be put through repeated trials with a therapy that doesn’t work for them.

HFA'S ADVOCACY EFFORTS TO SECURE PATIENT PROTECTIONS:

HFA participates with other consumer groups in the [SAIM coalition](#), which seeks common-sense limits on step therapy at the state level. More than 30 states now require some form of protections against step therapy, often including model language endorsed by SAIM requiring insurers to respond to exceptions requests within 72 hours (or 24 hours for urgent cases). HFA also participates in the Safe Step Coalition, which advocates for similar guardrails at the federal level.

HFA will continue working with member organizations engaging in state-level advocacy around step therapy and related barriers to access (such as burdensome prior authorization requirements, non-medical switching, copay accumulator adjusters).

WHAT CAN YOU DO?

- Report problems to [Project CALLS](#). Help HFA tell the story of why step therapy protections, and other aspects of fair health plan design, are important to people with bleeding disorders.
- Build relationships with potential allies in your state (other patient groups, Rare Disease Advisory Council, etc.) and with relevant state regulators.

Resources:

- SAIM Coalition, [Concerns with Step Therapy](#)
- Aimed Alliance, [Step Therapy](#)